		* , * *
1	KAMALA D. HARRIS	
2	Attorney General of California THOMAS L. RINALDI	*
3	Supervising Deputy Attorney General SYDNEY M, MEHRINGER	*
4	Deputy Attorney General	
	State Bar No. 245282 300 So. Spring Street, Suite 1702	
5	Los Angeles, CA 90013 Telephone: (213) 897-2537	
6	Facsimile: (213) 897-2804 E-mail: Sydney.Mehringer@doj.ca.gov	
7	Attorneys for Complainant	
8		RE THE
9	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS	
10	STATE OF C	CALIFORNIA
11	To do North Selection Assistant	G
	In the Matter of the Accusation Against:	Case No. 5327
12	ROSEBILL PHARMACY CORP. DBA MID VALLEY PHARMACY; FRANK PO	3
13	KEI WONG 2519 Royal Avenue	ACCUSATION
14	Simi Valley, CA 93065	Λ.
15	Pharmacy Permit No. PHY 47423,	
16	and	
17	FRANK PO KEI WONG	*
18	2519 Royal Avenue Simi Valley, CA 93065	*
19	Pharmacist License No. RPH 43505	
20	Respondents.	
21		
22	Complainant alleges:	ч
23	PARTIES	
24	Virginia Herold ("Complainant") brings this Accusation solely in her official capacity	
25	as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.	
26	2. On or about July 17, 2006, the Board of Pharmacy issued Pharmacy Permit Number	
27	PHY 47423 to Rosebill Pharmacy Corp. dba Mid Valley Pharmacy with Frank Po Kei Wong as	
28	President and Pharmacist-in-Charge ("Respondent Pharmacy"). The Pharmacy Permit was in full	
		1

force and effect at all times relevant to the charges brought herein and will expire on July 1, 2015, unless renewed.

3. On or about July 30, 1990, the Board of Pharmacy issued Pharmacist License Number RPH 43505 to Frank Po Kei Wong ("Respondent Wong"). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on September 30, 2015, unless renewed.

# **JURISDICTION**

- 4. This Accusation is brought before the Board of Pharmacy ("Board"), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.
  - 5. Section 4300.1 of the Code states:

"The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license."

- 6. Section 4300 of the Code states, in pertinent part:
- "(a) Every license issued may be suspended or revoked.
- "(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
  - "(1) Suspending judgment.
  - "(2) Placing him or her upon probation.
  - "(3) Suspending his or her right to practice for a period not exceeding one year.
  - "(4) Revoking his or her license.
- "(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper."

### STATUTES AND REGULATIONS

- 7. Section 4115, subdivision (e) of the Code states:
- "(e) No person shall act as a pharmacy technician without first being licensed by the board as a pharmacy technician."
  - 8. Section 4301 of the Code states, in pertinent part:

"The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

"(j) The violation of any of the statutes of this state, or any other state, or of the United States regulating controlled substances and dangerous drugs.

"(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency."

- 9. Health and Safety Code section 11165, subdivision (d) states:
- "(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:
- "(1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States

  Department of Health and Human Services, and the gender, and date of birth of the ultimate user.

"(2) The prescriber's category of licensure, license number, national provider		
identifier (NPI) number, if applicable, the federal controlled substance registration number, and		
the state medical license number of any prescriber using the federal controlled substance		
registration number of a government-exempt facility.		

- "(3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.
  - "(4) National Drug Code (NDC) number of the controlled substance dispensed.
  - "(5) Quantity of the controlled substance dispensed.
- "(6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code, if available.
  - "(7) Number of refills ordered.
- "(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.
  - "(9) Date of origin of the prescription.
  - "(10) Date of dispensing of the prescription."
  - 10. California Code of Regulations, title 16, section 1707.5, subdivision (d) states:
- "(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter."
  - 11. California Code of Regulations, title 16, section 1715 states, in pertinent part:
- "(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1

of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

- "(c) The components of this assessment shall be on Form 17M-13 (Rev. 01/11) entitled "Community Pharmacy Self-Assessment Hospital Outpatient Pharmacy Self-Assessment" and on Form 17M-14 (Rev. 01/11) entitled "Hospital Pharmacy Self-Assessment" which are hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.
- "(d) Each self-assessment shall be kept on file in the pharmacy for three years after it is performed."
  - 12. Code of Federal Regulations, title 21 section 1304.11 states, in pertinent part:
- "(a) General requirements. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.
- "(b) Initial inventory date. Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this

section as applicable. In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory.

"(c) Biennial inventory date. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date."

### COST RECOVERY

13. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

### BACKGROUND FACTS

- 14. On or about February 28, 2014, an agent of the Board checked the Controlled Substance Utilization Review and Evaluation System ("CURES") for Respondent Pharmacy's compliance with the requirement that it submit Schedule II, III, and IV controlled substance prescription data to the California Department of Justice. The Pharmacy Compliance Report showed that Respondent Pharmacy had only submitted controlled substance prescription data one time: for the months of April, May, and June 2013 on June 13, 2013.
- 15. On or about May 16, 2014, a Board Inspector requested a CURES Pharmacy
  Compliance Report for Respondent Pharmacy. On or about May 27, 2014, the Board Inspector
  received the Pharmacy Compliance Report. The Report showed that Respondent Pharmacy had
  submitted controlled substance prescription data for April, May, and June 2013 on June 13, 2013.
  The Report also showed that Respondent Pharmacy had submitted controlled substance
  prescription data for July through December 2013 on April 30, 2014 and January through March
  2014 on April 30, 2014.
- 16. On or about June 12, 2014, a Board Inspector conducted an inspection at Respondent Pharmacy. Pharmacy technician Steven Carrillo (TCH 34924) was present at the pharmacy that day. The Board Inspector discovered that Mr. Carrillo's pharmacy technician registration was

cancelled and had expired on December 31, 2013. Nevertheless, Mr. Carrillo was still working at Respondent Pharmacy in the capacity as a pharmacy technician.

- 17. During the inspection, the Board Inspector asked Respondent Wong for the Community Pharmacy Self-Assessment form but Respondent Wong could only produce a Self-Assessment from 2007. The Board Inspector also asked Respondent Wong for the biennial Drug Enforcement Administration ("DEA") Inventory but Respondent Wong was only able to provide a perpetual log of the pharmacy's Schedule II controlled substances. Further, the Board Inspector asked Respondent Wong for Respondent Pharmacy's required policies and procedures. Certain policies and procedures were missing, including a policy and procedure regarding providing interpretive services.
- 18. Also during the inspection, the Board Inspector discussed the CURES reporting issues with Respondent Wong and Mr. Carrillo. Mr. Carrillo stated that he had been attempting to submit data to Atlantic Associates<sup>2</sup> but due to technical difficulties, the data was not transmitting. However the only controlled substance prescription data that Respondent Pharmacy was able to produce in addition to the June 13, 2013 and April 30, 2014 data that had already been submitted was a report created on September 30, 2011 with a date range of June 1, 2011 through September 30, 2011.

#### FIRST CAUSE FOR DISCIPLINE

### (Failure to Conduct Pharmacy Self-Assessment)

19. Respondent Pharmacy and Respondent Wong are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1715, on the grounds of unprofessional conduct in that at the time of the Board inspection on June 12, 2014, Respondent Pharmacy and Respondent Wong did not have completed Community Pharmacy Self-Assessment forms for 2009, 2011, and 2013. A Self-Assessment must be completed before July 1 of every odd-numbered year of the pharmacy's compliance with

Atlantic Associates is the third party administrator for submitting data to CURES.

<sup>&</sup>lt;sup>1</sup> Mr. Carrillo provided documentation showing that he had submitted payment for his license renewal but the payment was late because of a change of address.

state and federal pharmacy law. Complainant incorporates by reference Paragraphs 14 through 18 as though fully set forth herein.

#### SECOND CAUSE FOR DISCIPLINE

# (Failure to Comply with Inventory Requirements)

20. Respondent Pharmacy and Respondent Wong are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with Code of Federal Regulations, title 21, section 1304.11, subdivision (c), on the grounds of unprofessional conduct in that at the time of the Board inspection on June 12, 2014, Respondent Pharmacy did not have a completed biennial DEA controlled substance inventory from 2007 to 2014. A new inventory of must be taken of all stocks of controlled substances on hand at least every two years. Complainant incorporates by reference Paragraphs 14 through 18 as though fully set forth herein.

## THIRD CAUSE FOR DISCIPLINE

# (Failure to Report to the Controlled Substance Utilization Review and Evaluation System)

21. Respondent Pharmacy and Respondent Wong are subject to disciplinary action under Code section 4301, subdivision (j), in conjunction with Health and Safety Code section 11165, subdivision (d), on the grounds of unprofessional conduct in that at the time of the Board inspection on June 12, 2014, Respondent Pharmacy had not submitted weekly controlled substance prescription data to the California Department of Justice, through CURES. Respondent Pharmacy had only submitted limited data on June 13, 2013 and April 30, 2014. Complainant incorporates by reference Paragraphs 14 through 18 as though fully set forth herein.

# FOURTH CAUSE FOR DISCIPLINE

## (Employment of an Unlicensed Pharmacy Technician)

22. Respondent Pharmacy and Respondent Wong are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with Code section 4115, subdivision (e), in that at the time of the Board inspection on June 12, 2014, Respondent Pharmacy and Respondent Wong employed Steven Carrillo as a pharmacy technician, even though Mr. Carrillo's pharmacy technician registration was cancelled and expired. Complainant incorporates by reference Paragraphs 14 through 18 as though fully set forth herein.

# 2 3

4

5 6

7

8 9

10

11

12 13

14 15

16

17

18

19 20

21

22 23

24

25

26 27

28

LA2014512854 51650171.doc

### FIFTH CAUSE FOR DISCIPLINE

# (Failure to Have Translation Policy and Procedure)

Respondent Pharmacy and Respondent Wong are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1707.5, subdivision (d), in that at the time of the Board inspection on June 12, 2014, Respondent Pharmacy did not have in place policies and procedures for interpretive services for its customers. Respondent Pharmacy was required to have policies and procedures in place to help patients with limited or no English proficiency understand the information on prescription labels in the patient's language. Complainant incorporates by reference Paragraphs 14 through 18 as though fully set forth herein.

# PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged. and that following the hearing, the Board of Pharmacy issue a decision:

- Revoking or suspending Pharmacy Permit Number PHY 47423, issued to Rosebill Pharmacy Corp. dba Mid Valley Pharmacy with Frank Po Kei Wong as President and Pharmacistin-Charge;
- Revoking or suspending Pharmacist License Number RPH 43505, issued to Frank Po Kei Wong; and
- Ordering Mid Valley Pharmacy and Frank Po Kei Wong to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;
  - Taking such other and further action as deemed necessary and proper.

Executive Officer Board of Pharmacy

Department of Consumer Affairs

State of California

Complainant